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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,115	06/23/2005	Ola Karlsson	1103326-0781	8848

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PATENT DEPARTMENT
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EXAMINER	
WU, IVES J	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,115	KARLSSON ET AL.	
	Examiner	Art Unit	
	Ives Wu	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-16,27-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-16,27-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

(1). Applicants' Amendments and Remarks filed on 08/27/2007 have been received. Claims 3 - 6 are amended. Claims 1- 2 and 17- 26 were cancelled previously.

Consequently, the rejections of claims 3-16 and 27-32 in prior Office Action dated 02/27/2007 is withdrawn in response to the Remarks of 08/27/2007.

However, a new ground of rejections for claims 3-16 and 17-26 is introduced herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(2). **Claims 7 - 8** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims 7 and 8, it recites: An aqueous polymer dispersion prepared by polymerizing a mixture of monomers consisting: - three monomers". It is well known in the art that components other than monomers are required for the preparation of aqueous polymer dispersion, it is also well known in the art that impurities would exist after the polymerization. Although the impurities can be removed, however, it is not completely removed in a common sense. Applicants use the word: "**consisting**" in instant claims 7 and 8, which excludes any other components even in ppb amount - it means non-existent. Therefore, it renders issue of enablement.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(3). **Claims 7 - 8** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 7 and 8, it recites: "An **aqueous** polymer dispersion prepared by polymerizing a mixture of monomers consisting: - three monomers". However, component of water is excluded in the instant claims 7 and 8. One of ordinary skills in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(4). **Claims 3-6, 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinecke et al (US04056497) in view of Greenwald et al (US03944513).

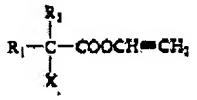
Reinecke et al (US004056497) disclose a acrylic ester copolymers obtained by copolymerizing acrylic esters with α-haloalkanecarboxylic acid vinyl esters and α,β-ethylenically unsaturated carboxylic acids and optionally other unsaturated monomers in aqueous dispersion. The copolymers can be cross-linked with alkalies after the polymerization (Abstract, line 1-5).

The present patentee's invention provides a process for the preparation of aqueous copolymer dispersions capable of being cross-linked in the presence of alkalies by polymerization of a mixture of:

a. 60 to 95 wt%, calculated on the monomer mixture, of at least one acrylic acid ester and/or methacrylic acid ester of a saturated aliphatic alcohol having from 1 to 20 carbon atoms,

b. 0 to 40 wt%, calculated on the monomer mixture, of monomers the homopolymers of which have 2nd order Tg of from –40°C to +150 °C and

c. 0.1 to 10 wt%, calculated on the monomer mixture, of an α-haloalkanecarboxylic acid vinyl esters of the formula (I)

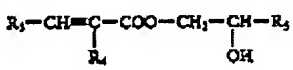


(I)

wherein R_1 and R_2 each represents hydrogen or an alkyl radical having from 1 to 5 carbon atoms and X is fluorine, chlorine, bromine or iodine, in aqueous dispersion in the presence of emulsifiers and/or protective colbids and of free radical initiators, which process comprises using as further reactive monomers

d. 0.1 to 10 wt%, calculated on the monomer mixture of, α,β-ethylenically unsaturated carboxylic acids having from 3 to 8 carbon atoms or their partial ester with saturated aliphatic alcohols having from 1 to 20 carbon atoms and,

e. 0 to 10 wt%, calculated on the monomer mixture, of monomers containing hydroxyl groups and having the formula (II)



(II)

wherein R_3 is hydrogen, a methyl group or the group $-COOR_6$, R_4 and R_5 each is hydrogen or a methyl group and R_6 is hydrogen or an alkyl group having from 1 to 12 carbon atoms.

(Col. 1, line 57 – Col. 2, line 32)

The dispersions of patentee's invention are prepared by free radical polymerization of the monomers in **aqueous dispersion using emulsifiers**, protective colloids and, optionally regulators (Col. 3, line 12-15). The polymerization temperature is within the range of from 0 °C to + 100 °C, preferably from 20° to 80°C (Col. 3, line 27-29). A foil of polyethylene terephthalate of a 2.5 cm X 20 cm dimension was provided with an adhesive layer 0.3 mm thick (application in wet state). After drying, the foil was joined under slight pressure to a carefully cleaned steel sheet for measurement of the resistance to peeling (kp/2.5 cm) (Col. 6, line 28-34). The dispersion and the film obtained from the dispersion were extracted with dioxane for determination of the degree of crosslinking (Col. 6, line 51-53).

As to the components of acrylic acid or an ester in the range 40 to 80 wt% , methacrylic acid or an ester in the range 20 to 60 wt% in **claims 3-4**, Reinecke et al disclose component (a) from 60 to 95 wt% including at least one acrylic acid ester and methacrylic acid ester of a saturated aliphatic alcohol having C_{1-20}. The range of 60 to 95wt% would include the acrylic acid ester such as ethyl acrylate in the range from 40 to 80 wt% and methacrylic acid ester such as methyl methacrylate in the range from 20 to 60 wt% as claimed.

As to the polymerizable surfactant in **claims 3-4** and **31**, Reinecke et al disclose the component (e) having the formula (II) which is equivalent to formula (I) as claimed, when the setting of patentee's formula (II) are R_3 = H atom, R_4 = H atom or methyl group, R_5 = H, and setting of applicant's formula (I) are R_2 = H atom, m = 1. Since the disclosure of the monomer by Reinecke et al is identical to the formula (I) as claimed. It is reasonable to presume that the component (e) of Reinecke et al would fulfill the utility to be a polymerizable surfactant as presently claimed in light of their chemical similarity. The burden is shifted to applicants to establish that the polymerizable surfactant of the present claims is not the same as or obvious as that set forth by Reinecke et al.

As to substantially free of residual emulsifying agent which is removed after the polymerization reaction in **independent claims 3-4**, Reinecke et al is silence about removal of emulsifier.

However, Greenwald et al (US03944513) **teach** purification of polymer dispersions with adsorbent carbon particles (Title).

The advantage of removing emulsifiers is for the reasons that aqueous dispersions of vinyl polymers often contain impurities, including volatile and nonvolatile materials, which may impart undesirable properties to the polymer such as haze, color and odor, and detract from desirable properties such as strength, toughness, flexibility, water resistance and electrical properties. Such impurities may include un-polymerized monomers, initiators such as potassium persulfate, chain transfer agent such as mercaptans, emulsifiers, impurities introduced with these materials, and the reaction products or degradation products thereof. The impurities may be in or on the polymer particles as well as in the aqueous phase (Col. 1, line 9-21).

Therefore, it would have been obvious at time of the invention to remove the emulsifier disclosed by Greenwald et al for the aqueous acrylate ester copolymer of Reinecke et al in order to obtain the above-cited advantage.

As to the aqueous polymer dispersion, monomers, their wt percentage, formula (I) of the monomer and emulsifier being removed after the polymerization in **claims 5** and **6**, the disclosure of Reinecke et al (US004056497) is incorporated herein by reference, the most subject matters as currently claimed have been recited in applicants' claims 3 and 4, and have been discussed therein.

As to the molecular weight of emulsifier to be less than 15kD in **claims 5** and **6**, in view of substantially identical aqueous polymer dispersion disclosed by Reinecke et al, and by applicants, it is examiner's position to believe that the emulsifier of prior art would inherently possess the molecular weight as claimed. Since USOPTO does not have facilities to perform the measurement, the burden now is shifted to applicants to prove otherwise. *In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).*

(5). **Claims 9-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teaching of Reinecke et al (US004056497), Greenwald et al (US03944513) and Barry et al (US005055306).

As to step of applying the aqueous dispersion to the surface of the dosage form and removing water from the aqueous dispersion to obtain film in a pharmaceutical coating film in **claim 9**, Barry et al (US005055306) disclose the coating being prepared by forming a solution and mixing it with a dispersion of a water insoluble but water swellable acrylic polymer. The aqueous mixture is then used to coat the dried granules, and the coated granules are subsequently dried (Col. 8, line 37-43). Obviously, the water is removed and film is formed after the coating is dried.

Barry et al **do not teach** the use of acrylic ester copolymer of Reinecke et al for the coating in pharmaceutical formulation.

The advantage of using the acrylic ester copolymer taught by Reinecke et al is pressure-sensitive adhesive of high heat stability (Abstract, line 6-7).

Therefore, it would have been obvious at time of the invention to use the acrylic ester copolymer of Reinecke et al et al for the coating film of pharmaceutical formulation of Barry et al in order to obtain the above-mentioned advantage. Moreover, the acrylic ester polymer taught by Barry et al is a genus, the acrylic ester copolymer taught by Reinecke et al is species, one of ordinary skills in the art would expect all species work successfully for the genus, motivated by a reasonable expectation of success. *In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).*

As to the pharmaceutical formulation in **claim 10**, Barry et al (US005055306) **teach** a sustained-release formulation comprising a core comprising one or more pharmacologically active substances and preferably one or more excipients; and a coating covering substantially the whole surface of the core comprising 100 parts of a water insoluble but water swellable acrylic polymer and from 20 to 70 parts of a water soluble hydroxylated cellulose derivative (Abstract, line 9-17). The acrylic polymer component of the coating is preferably neutral and may comprise a homopolymer or a copolymer, for instance of acrylic acid esters or methacrylic acid esters. Preferably, the acrylic polymer is provided as an aqueous dispersion (Col. 6, line 60-64).

As to limitation of **claim 11**, Barry et al **teach** a granular sustained-release formulation of a pharmacologically active substance presented in the form of a tablet, tablet comprising sufficient granules to provide a predetermined dose or number of dose of pharmacologically active substance and effervescent or water-dispersible ingredients (Abstract, line 1-6). The coating is prepared by forming a solution of, for example, a water soluble hydroxylated cellulose derivative and mixing it with a dispersion of a water swellable acrylic polymer. The aqueous mixture is then used to coat the dried granules, and the coated granules are subsequently dried. (Col. 8, line 38-45). It will be appreciated that the term "granules" as used is intended to also cover other similar particles that might, in conventional sustained-release formulations, normally be referred to as beads or pellets, etc (Col. 8, line 64-68).

As to limitation of **claim 12**, Barry et al disclose the sustained-release formulation (Title).

As to limitation of **claims 13** and **14**, Barry et al disclose, for instance, the pharmacologically active substances that can be used in the sustained-release formulations includes: drug acting on the gastrointestinal system (such as cimetidine), the cardiovascular

system (such as anti-arrythmics e.g. verapamil; beta-adrenoceptor blockers e.g. propranolol, atenolol; anti-hypertensives e.g. methyldopa, levodopa and prazosin) (Col. 7, line 6-13).

(6). **Claims 15** and **16** is rejected under 35 U.S.C. 103(a) as being unpatentable over combined teaching of Reinecke et al (US004056497), Greenwald et al (US03944513), Barry et al (US005055306), further in view of Chen (US005939578A). Evidenced by Jonsson et al (US004957745).

As to the limitation of **claims 15** and **16**, Barry et al **do not teach** the beta-blocking adrenergic agent to be metoprolol salts such as tartate, succinate, fumarate or benzoate salt.

However, Chen **teach** a comparative results in beta-adrenoceptor blocking activity to show the patentee's vasomolol with other beta-adrenoceptor blockers such as metoprolol and stenolol and propranolol (Col. 5, line 18-21).

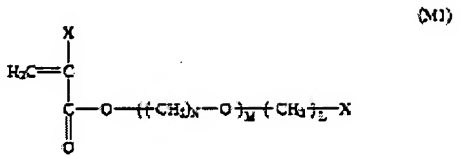
Therefore, it would have been obvious at time the invention was made to include the metoprolol of Chen in the beta-adrenoceptor blockers of Barry et al in view of their functional equivalent beta-adrenergic blockers, motivated by reasonable expectation of success. *In re O'Farrell,* 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

As to the pharmaceutical acceptable metoprolol salts in **claim 16,** it is well known in the art that metoprolol salts including tartrate, succinate, fumarate or benzoate as evidenced by Jonsson et al (US004957745 – Col. 3, line 17-22).

(7). **Claims 27-30** and **32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinecke et al (US04056497) in view of Greenwald et al (US03944513), further in view of Contrada et al (US06646046B2) and Zellstoffwerke (GB01141165).

As to the limitation of dependent **claims 27-30** and **32**, Reinecke et al **do not teach** the repeating units in his formula (II) (Col. 2, line 24-28) and an alkoxy group with C_{1-20} for terminal group.

However, Contrada et al (US06646046B2) **teach** a monomer M1 compound used in aqueous pressure-sensitive adhesive composition with the following formula:



where X: hydrogen or an alkyl group, N: 1 – 4, M: 1 – 20, L: 0 – 5 (Col. 3, line 38-54) such as lauroxy polyethyleneglycol monoacrylate, methoxy ethyl acrylate and methoxy polyethyleneglycol methacrylate (Col. 5, line 2-5). Zellstoffwerke (GB01141165) also **teaches** an acrylic films comprising component of an ester of a polyethoxylated product containing at least one acrylic or methacrylic acid ester group (page 1,line 62-64).

The advantage of using monomer M_1 of Contrada et al is to provide a water-soluble pressure-sensitive adhesive composition having balanced adhesive properties (Col. 2, line 56-59). Furthermore, M_1 monomer of Contrada et al would include the component (e) of Reinecke et al by the setting of N = 2, M = 1, L = 0 and X = H atom in the M_1 monomer formula (Col.3, line 38-54).

The ester of a polyethoxylated product containing at least one acrylic or methacrylic acid ester group taught by Zellstoffwerke (GB01141165) also include the component (e) of Reinecke et al (US004056497) when number of repeating units is 1.

Therefore, it would have been obvious at time the invention was made to use the M1 monomer compound of Contrada et al for the component (e) of Reinecke et al in order to obtain the above-mentioned advantage. Moreover, in view of their functional equivalent component for acrylic ester copolymer disclosed by Reinecke et al, Contrada et al and Zellstoffwerke, it also would be obvious to use the M1 monomer of Contrada et al and ester of a polyethoxylated product containing at least one acrylic or methacrylic acid ester group taught by Zellstoffwerke (GB001141165) to take place of component (e) of aqueous dispersion of Reinecke et al based on their interchangeability for acrylic ester copolymer, motivated by reasonable expectation of success. *In re O'Farrell,* 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

Response to Arguments

Applicant's arguments, see pages 9-10, Remarks, filed 08/27/2007, with respect to the rejection(s) of claim(s) s 3-8 under 102 rejection in view of Reinecke et al (US04056497) and

103 rejection in view of combined teaching Lalk et al (US03234039), Amen et al (US03086956) and Tanaka et al (US036717689) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Reinecke et al (US04056497) and Greenwald et al (US03944513).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ives Wu whose telephone number is 571-272-4245. The examiner can normally be reached on 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571-272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Examiner: Ives Wu
Art Unit: 1797
Date: October 27, 2007

DUANE SMITH
PRIMARY EXAMINER
10-29-07